



CERTIFICATE OF ANALYSIS

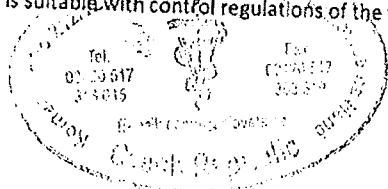
Product: **Biocan Novel DHPPI/L4 vakcina A.U.V.**

Batch No.: 47 58 24
 Expiry: 18.04.2019
 Date of production: 19.04.2017

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Freeze-dried fraction			
Appearance	Spongy matter, white colour.		
Residual humidity	0.5 - 3 %		conforms
Vacuum	Residual pressure must be lower than 2.66 Pa.		2.0 %
Sterility	Vaccine must be sterile.		conforms
Mycoplasma	Vaccine must be free from <i>mycoplasma</i> .		sterile
Extraneous agents	Free from extraneous agents.		conforms
Virus titre	Function: To determine the virus titre (potency) of each CAV-2, CDV, CPIV-2 and CPV-2b antigen in the finished product.		conforms
CDV	min. 10 ^{4.0} TCID ₅₀ -max. 10 ^{5.1} TCID ₅₀	min. 10 ^{3.1} TCID ₅₀ - max. 10 ^{5.1} TCID ₅₀	10 ^{4.8} TCID ₅₀
CPV	min. 10 ^{5.1} TCID ₅₀ - max. 10 ^{5.6} TCID ₅₀	min. 10 ^{4.3} TCID ₅₀ - max. 10 ^{5.6} TCID ₅₀	10 ^{5.1} TCID ₅₀
CAV-2	min. 10 ^{4.2} TCID ₅₀ - max. 10 ^{5.3} TCID ₅₀	min. 10 ^{3.6} TCID ₅₀ - max. 10 ^{5.3} TCID ₅₀	10 ^{5.1} TCID ₅₀
CPIV-2	min. 10 ^{3.6} TCID ₅₀ - max. 10 ^{5.1} TCID ₅₀	min. 10 ^{3.1} TCID ₅₀ -max. 10 ^{5.1} TCID ₅₀	10 ^{4.1} TCID ₅₀
Identity	Function: The test is performed to confirm presence of each CAV-2, CDV, CPIV-2 and CPV antigen in the finished product.		conforms
CDV	Neutralization Index has to be equal or higher than 2 log ₁₀ and/or specific immunofluorescence has to be seen in the cell culture infected with CDV.		4.8
CAV-2	Neutralization Index has to be equal or higher than 2 log ₁₀ and/or specific immunofluorescence has to be seen in the cell culture infected with CAV-2.		5.1
CPV-2b	The CPV type must be CPV 2a, b, c group.		conforms
CPIV-2	Neutralization Index has to be equal or higher than 2 log ₁₀ and/or specific immunofluorescence has to be seen in the cell culture infected with CPIV.		4.1
Liquid fraction			
Appearance	Whitish liquid with easily shakeable sediments.		
Extractable volume	Minimum 1 ml		conforms
Airtightness	The glass vial must be hermetically sealed.		1.1 ml
Aluminium content *	2 mg/ml (1.8 - 2.2 mg/ml)		conforms
Sterility	Vaccine must be sterile.		2.0 mg/ml
<i>Leptospira</i> inactivation *	No live <i>Leptospira</i> .		sterile
Formaldehyde detection *	The formaldehyde detected has to be below 0.01%.		conforms
<i>Leptospira</i> Identity	Vaccine stimulates the production of specific antibodies against each <i>Leptospira</i> serovar.		< 0.01 % conforms
L. Icterohaemorrhagiae	Minimum of 1:64 ALR geometric mean titre, for each <i>Leptospira</i> serovar.	Minimum of 1:51 ALR geometric mean titre for L. Icterohaemorrhagiae.	1: 102
L. Canicola		Minimum of 1:51 ALR geometric mean titre for L. Canicola.	1: 102
L. Bratislava		Minimum of 1:51 ALR geometric mean titre for L. Bratislava.	1: 161
L. Grippotyphosa		Minimum of 1:40 ALR geometric mean titre for L. Grippotyphosa.	1: 203
Reconstituted Vaccine			
Appearance	Pinkish or yellowish colour with light opalescence.		
pH	6.8 - 7.8		conforms
			7.3

* tests carried out during manufacturing proces of liquid fraction
 I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 465.



19/10/2017
 Mgr. Hana Nezvalová
 HEAD of QC, QP

Bioveta, a.s. Ivanovice na Hané	Biocan Novel DHPPi/L4, lyophilisate and solvent for suspension for injection for dogs	Ident. kód: BPR00016 Strana: 1 z 35 Počet příloh: 0 Verze: V001 Výtisk číslo:
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1. MEMBER STATE SPECIFIC INFORMATION

Identification number for batch to be placed on the market in the Member State (if packaging number different from final number in section 2):	47 58 24
Marketing authorisation number issued by (Member State/EU)	3561/1/14 NÉBIH ÁTI (1 adag)
Target species:	Dog
Total number of containers in this batch (pcs):	19 000 pcs
Number of containers the release is applied for:	1 000 x 10 x 1 dose
Number of doses per container:	one
Number of samples for the competent authority:	--
Date of expiry:	18.04.2019
Name and address of Marketing Authorisation holder (if different from manufacturer in section 2)	

Bioveta, a.s. Ivanovice na Hané	Biocan Novel DHPPi/L4, lyophilisate and solvent for suspension for injection for dogs	Ident. kód: BPR00016 Strana: 2 z 35 Počet příloh: 0 Verze: V001 Výtisk číslo:
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2. SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name:	Biocan Novel DHPPi/L4, lyophilisate and solvent for suspension for injection for dogs
Ph.Eur.	Vaccina ad usum veterinarium.
Nature of product:	Vaccine against canine distemper (CDV), inf. hepatitis (CAV-1), inf. laryngotracheitis (CAV-2), parvovirus (CPV-2b), parainfluenza (CPIV-2) virus and against leptospirosis in dogs inactivated.
Batch number(s) of finished product:	47 58 24
Pharmaceutical form of final product:	Injection
Type of final container:	3 ml glass vials
Date of start of period of validity	19.04.2017 (Blending)
Shelf life:	24 months
Storage temperature:	Store in a dark and dry place at the temperature between 2 °C and 8 °C. Do not freeze.
Name and address of manufacturer:	Bioveta, a.s. Komenského 212/12 683 23 Ivanovice na Hané, Czech Republic
Name and address of the batch control site	/

Bioveta, a.s. Ivanovice na Hané	Biocan Novel DHPPi/L4, lyophilisate and solvent for suspension for injection for dogs	Ident. kód: BPR00016 Strana: 3 z 35 Počet příloh: 0 Verze: V001 Výtisk číslo:
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3. PRODUCTION INFORMATION

Summary information scheme on batch specific production data including data of different production stages, production sites and identification numbers.

Product name:

Biocan Novel DHPPi/L4, lyophilisate and solvent for suspension for injection for dogs.

Product batch number: 47 58 24

Component and ID No.	Site(s) of manufacture	Date of manufacture
DHPPi component (batch no.66 54 24 A)		
Canine distemper virus 47/2016/CDV 57/2016/CDV 84/2017/CDV	Bioveta, a.s.	11.11.2016 16.12.2016 18.4.2017
Virus laryngotracheitidis contagiosae canis 56/2017/CAV-2	Bioveta, a.s.	24.3.2017
Parvovirus enteritidis canis, strain 2b 71/2016/CPV-2b 82/2017/CPV-2b	Bioveta, a.s.	28.11.2016 30.1.2017
Virus parainfluenzae canis 27/2015/CPiV-2 28/2015/CPiV-2 52/2016/CPiV-2 63/2016/CPiV-2	Bioveta, a.s.	8.9.2015 12.9.2015 27.1.2016 9.3.2016
Lyophilisation medium 93 53 24 94 53 24	Bioveta, a.s.	22.3.2017 29.3.2017
L4 component (batch no.79 55 24 A)		
<i>Leptospira Icterohaemorrhagiae</i> 36/2017/ICT1089	Bioveta, a.s.	2.5.2017
<i>Leptospira Grippotyphosa</i> 36/2017/GRI1091	Bioveta, a.s.	2.5.2017
<i>Leptospira Canicola</i> 36/2017/CAN1090	Bioveta, a.s.	3.5.2017
<i>Leptospira Bratislava</i> 36/2017/BRA1088	Bioveta, a.s.	3.5.2017
Aluminium hydroxide gel	Vac 20	-